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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,614	08/13/2001	Heng Zhong	S-31514A	7523

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EXAMINER	
KALLIS, RUSSELL	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/928,614	ZHONG ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cov r sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,14-16,18,22-29 and 51-64* is/are pending in the application.

4a) Of the above claim(s) *14-16 and 25-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,18,22-24,29 and 51-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1, 14-16, 18, 22-29 and 51-64 are pending. Claims 14-16 and 25-28 are withdrawn. Claims 2-13, 17, 19-21 and 30-50 are cancelled. Claims 1, 18, 22-24, 29, and 51-64 are examined.

Claim Rejections - 35 USC § 103

The rejection of Claims 1-13, 18-24, and 29 under 35 U.S.C. 103(a) as being unpatentable over Tuli R. *et al.*, U.S. Patent 6,242,257 filed May 22, 1997 in view of Rangan is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 112

The rejection of Claims 1-13, 18-24, and 29 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in part in view of Applicant's amendments and arguments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 64 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The added claimed material which is not supported by the original disclosure is as follows: Newly added Claim 64 recites wherein said dicotyledonous plant tissue is from a plant of any family selected from *Curcurbitaceae, Chenopodiaceae,* and *Asteraceae* while the specification only supports *Curcurbitaceae,* and *Chenopodiaceae* as preferred source of transformable plant tissue. Thus, the claims are drawn to NEW MATTER.

Claims 1, 18, 22-24, 29, and 51-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of *Agrobacterium* mediated transformation of multiple shoot cultures of melon, watermelon, and squash from *Cucurbitaceae* and multiple shoot cultures of sugar beet from *Chenopodiaceae* and sunflower, wherein said multiple shoot are cultures generated from meristematic tissue-containing explants; does not reasonably provide enablement for non-Agrobacterium-mediated transformation methods (i.e. biolistic methods, protoplast fusion, liposomal methods, pollen transformation or methods of soaking seeds in solutions of DNA) of melon, watermelon, and squash from *Cucurbitaceae* and multiple shoot cultures of sugar beet from *Chenopodiaceae* and sunflower. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims a method of transforming and regenerating a dicotyledonous plant using any transformation method including either *Agrobacterium* infection or any non-biologically mediated method for transformation of multiple shoot cultures generated from meristematic tissue or callus on culture medium having cytokinin levels from 0.01 mg/L to 25 mg/L, wherein the plant tissue is squash, melon, watermelon, sunflower, or sugarbeet; and a

method of transforming and regenerating a dicotyledonous plant by *Agrobacterium* transfection of any plant from plant families *Cucurbitaceae, Chenopodiaceae,* or *Asteraceae.*

Applicant teaches a method for *Agrobacterium* mediated transformation of multiple shoot meristematic cultures of squash, watermelon, melon, and sunflower and regeneration of transformed plants thereof (Examples 1-4, pages 29-36) and transformation and regeneration of viable and fertile sugar beet plants expressing GUS in T1 seeds (Example 5, pages 36-41); and provides prophetic guidance for the biolistic transformation of multiple shoot cultures from sugarbeet (Example 6, pages 43-44).

Applicant does not teach non-Agrobacterium mediated transformation methods of multiple shoot cultures (i.e. biolistic methods, protoplast fusion, liposomal methods, pollen transformation or methods of soaking seeds in solutions of DNA) of melon, watermelon, and squash from *Cucurbitaceae* or of sugar beet from *Chenopodiaceae* and sunflower.

The unpredictability inherent in adapting transformation methods with a particular tissue culture method is shown in the number of multiple insertion events at the same locus in the genome of a transformed plant with a high degree of rearrangements of the transforming DNA in almost all the lines recovered (Kohli A. *et al.,* PNAS, June 1998, Vol. 95; pages 7203-7208; see 7205 column 2, lines 29-37 and Table 1 page 7206). Although tDNA had been integrated, the extent that the formation of chimeric structure would result in a phenotype is unpredictable. Further, it is well known in the art that multiple insertion events give rise to gene silencing and often result in the reduction or elimination of expression of the desired gene, which is the exact opposite result of what was originally intended requiring further screening and experimentation.

Further, transformation methods are known to hinder the ability of known tissue culture methods to produce whole plants. It is well known in the art that direct DNA transfer transformation methods are inherently unpredictable and require rigorous testing (Potrykus I. *et al.*, Biotechnology 1990, pages 535-542; page 539 to 541, Examples 7-12, 14-17, and 19-21).

Furthermore, a recent review of particle bombardment methods teaches that meristem bombardment gives rise to chimeric structures, multiple insertions, and low efficiencies of transformation requiring excessive effort to screen through a multitude of chimeric plants and plants having multiple insertions (Taylor N. *et al.* DNA and Cell Biology, November 12, 2002; Vol. 21, pages 963-977; see page 969, column 1 line 42 to column 2, line 10; and page 972 column 1; see Multiple copy insertions and superfluous DNA integration).

Considering the absence of guidance provided for transformation of *Curbitaceae* and *Chenopodeae* species and sunflower by non-*Agrobacterium* means, and given the unpredictability in the art, undue trial and error experimentation would be required to screen through the myriad of chimeric plants produced by a multitude of non-exemplified non-*Agrobacterium* methods of transformation of *Curbitaceae* and *Chenopodeae* species and sunflower encompassed by the scope of the claims to find culturing and transformation conditions that would successfully recover a transformed plant with a non-chimeric transgene.

Applicant asserts that the Kohli reference is merely a study of integration patterns and no bearing on the transformation of plant cells (response page 8). Applicant does not respond to the Examiner's assertion that it is well known in the art that the multiple insertions and rearrangements described in the reference are a source of unpredictability.

Applicant asserts that the Potrykus reference is over ten years old and since then substantial improvements have been made in the technology, further stating that plants are routinely transformed by *Agrobacterium* methods and further cites Hansen (response page 8). *Agrobacterium* mediated DNA transfer into plants was not the subject of the scope of enablement rejection of the previous and current office action. Problems with direct DNA transfer are today still significant as argued supra i.e. Taylor *et al.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 24, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bordas M. *et al.* Transgenic Research, 1997; Vol. 6, No. 1, pages 41-50.

Bordas *et al.* teaches transformed melon, melon cells, and transgenic melon seeds therefrom (see Abstract and page 46, column 1). The prior art plants differ from the claimed plants, cells and seeds only by their method of manufacture. However, the claimed method of making the transformed melon, melon cells, and transgenic melon seeds would not distinguish them over the transformed melon plants, melon cells, and transgenic seeds taught by the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977).

The reference teaches all the limitations of Claims 22, 24, and 29.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Dodds J. et al. Experiments in Plant Tissue Culture; Cambridge University Press, 1982; pages 98-106.

Applicant broadly claims both untransformed and transformed multiple shoot cultures produced during the method of Claim 1.

Dodds teaches a method for culturing meristematic tissues of plants to form multiple shoot cultures (pages 98-106). Thus the reference teaches all the limitations of Claim 23. Amendment of Claim 23 to indicate that the shoot culture is transformed would obviate this rejection.

All claims are rejected.

Claims 1, 18, 51-64 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a method of transforming shoot cultures derived from meristematic tissues of squash, melon, watermelon, sunflower, or sugarbeet by *Agrobacterium* infection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
January 28, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638